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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,565

10/28/2003

Isaac Farr

200313766-1

9174

22879 7590 03/08/2007

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EXAMINER

LAMBELET, LAWRENCE EMILE

ART UNIT

PAPER NUMBER

1732

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/08/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/695,565

Applicant(s)

FARR ET AL.

Examiner

Lawrence Lambelet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 21-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Applicant's amendment filed on 12/1/2006 is acknowledged. Cancelled claims 11 and 13-20, amended claims 1, 2, 10 and 12, and new claims 21-27 are placed of record in the file. The rejection of claim 2 under 35 U.S.C. 112, 2<sup>nd</sup> is withdrawn in view of amendment. Claims 1-10, 12 and 21-27 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo et al (U.S. Patent Application Publication 2002/00157280), and further in view of Zheng (U.S. Patent Application Publication 2003/0235738).

Payumo et al, hereafter "Payumo", discloses a method of producing a structure, in this case an oral dosage form, as recited by claim 1. Payumo teaches the Solid Free-form Fabrication (SFF) technique of forming a three-dimensional object through successive layer depositions of powder and binder as shown in paragraph [0021]. Payumo further teaches that the powder may contain particles of binder in solid form and that the binder may include sodium alginate. In other words, an alginate-based

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powder is provided in the combined teachings of paragraphs [0026] and [0046]. The object thus formed with alginate-based material will have elastomeric (flexible) properties, by applicant's admission. See lines 5-6 on page 3 of the instant specification.

Examiner notes that Payumo teaches that binder may be a powder which is admixed with other particulate and is not necessarily a dispensed liquid. See paragraphs [0021] and [0025]. This creates some confusion with the instant claim terminology, wherein the term "binder" refers to the dispensed liquid component. Hereinafter, the term "liquid" will be used in the citation discussion where the meaning is "binder" in the sense of the instant claim.

Payumo teaches that the liquid is dispensed by a piezoelectric drop-on-demand printhead (ink jet printhead), as required by claim 1. See paragraph [0021].

Payumo does not teach that the alginate-based powder is 50-90% by weight of the combined material and that the liquid is 10-50% by weight, as required by claim 1.

Zheng teaches use of a composition for a rapid prototyping application, with specific mention of ink jet printing, wherein the powder to liquid ratio is 70% (powder is 41% of combined material), and wherein the powder component includes alginates. See paragraphs [0054], [0073] and [0074]. While the instant claim limitation recites 50% for the powder, a prima facie case exists on the basis of an expectation of equivalent results, absent evidence of the criticality of the powder contribution percent as claimed. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Payumo and Zheng are combinable because they are concerned with a similar technical field, namely rapid prototyping. It would have been obvious to one of ordinary skill in the art at the time of the invention to include the mixture ratios as taught by Zheng in the fabrication process of Payumo. The motivation to do so would have been to achieve a higher fabrication speed. See paragraph [0078] of Zheng.

Claims 2-10, 12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo in view of Zheng, and further in view of Schulman et al (U.S. Patent 6,808,659).

Payumo/Zheng teaches the method of claim 1, as discussed above.

Payumo/Zheng teaches that the powder includes cellulose (filler) in addition to the alginate compound, as required by claim 2. See paragraph [0024].

Payumo/Zheng teaches laying down a layer of powder and dispensing liquid onto predetermined regions of the powder bed, as required by claims 3, 4, and 5. See paragraph [0021].

Payumo/Zheng teaches that the liquid may include acrylic acid polymers (water retaining additive), as required by claim 6. See paragraph [0046].

Payumo/Zheng teaches that the alginate compound is sodium alginate, as required by claims 7 and 21. See paragraph [0046]. Sodium alginate can be a derivative of alginic acid.

Payumo/Zheng teaches that the liquid is aqueous-based (water constituting swelling agent), as required by claim 8. See paragraph [0046].

Payumo/Zheng teaches that the mixture may include polyethylene oxide (viscosity modifier), as required by claims 9 and 10. This is shown in paragraph [0046].

Payumo/Zheng does not teach the powder composition including a multivalent cation, as required by claim 2. Payumo further does not teach the multivalent cation in a range of about 0.5% to 30% by weight, or the filler in a range of 5% to 50% by weight, or the alginate compound in a range of 50% to 90% by weight, of the powder mixture, as required by claim 12.

Schulman et al, hereafter "Schulman", teaches that calcium phosphate (multivalent cation) is used as a filler at lines 14-29 in column 7. Schulman further teaches that the filler is up to 30% by weight of the composition. Since calcium phosphate functions as both cation and filler, the range satisfies the claim and leaves at least 70% balance for the alginate compound.

Payumo/Zheng and Schulman are combinable because they are concerned with a similar technical field, namely SFF. It would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Payumo/Zheng the powder ingredient yielding a multivalent cation, as taught by Schulman. The motivation would have been to simplify the process by combining filler and cation functions into a single material.

Claims 22-23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo in view of Zheng and Schulman as applied to claims 1-10,

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12 and 21, and further in view of Bredt et al (U.S. Patent Application Publication 2006/0230984).

Payumo/Zheng/Schulman teaches the method of claims 1-10, 12 and 21, as discussed above.

Payumo/Zheng/Schulman does not teach the ingredient of magnesium oxide, as required by claim 22, or of magnesium hydroxide, as required by claim 23.

Payumo/Zheng/Schulman further does not teach the ingredient of starch, as required by claim 25, or of polyethylene glycol, as required by claim 26.

Bredt et al '984, hereinafter "Bredt '984", teaches above ingredients in a 3D Printing application. See paragraphs [0041] and [0046].

Payumo/Zheng/Schulman are combinable because they are concerned with a similar technical field, namely, rapid prototyping. One of ordinary skill in the art at the time of the invention would have found it obvious to include the mixture ingredients as taught by Bredt '984 in the method of Payumo/Zheng/Schulman. The motivation to do would have been to rapidly form a solid composite. See paragraph [0041] of Bredt '984.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo in view of Zheng and Schulman as applied to claims 1-10, 12 and 21, and further in view of Bredt et al (U.S. Patent Application Publication 2005/0197431).

Payumo/Zheng/Schulman teaches the method of claims 1-10, 12 and 21, as discussed above.

Payumo/Zheng/Schulman does not teach the ingredient of silicon carbide fibers, as required by claim 27.

Bredt et al '431, hereinafter "Bredt '431", teaches silicon carbide fiber for a reinforcement material. See paragraph [0056].

Payumo/Zheng/Schulman are combinable because they are concerned with a similar technical field, namely, rapid prototyping. One of ordinary skill in the art at the time of the invention would have found it obvious to include the reinforcement ingredient as taught by Bredt '431 in the method of Payumo/Zheng/Schulman. The motivation to do would have been to add dimensional control. See paragraph [0056].

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Payumo in view of Zheng and Schulman as applied to claims 1-10, 12 and 21, and further in view of Hjelland (U.S. Patent Application Publication 2005/0038237).

Payumo/Zheng/Schulman teaches the method of claims 1-10, 12 and 21, as discussed above.

Payumo/Zheng/Schulman does not teach an alginate compound comprised of mannuroic and guluronic acid, as required by claim 24.

Hjelland teaches co-polymers of mannuronic and guluronic acid. See paragraph [0005].

Payumo/Zheng/Schulman are combinable because they are concerned with a similar technical field, namely, alginate materials. One of ordinary skill in the art at the time of the invention would have found it obvious to include the alginate production

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process taught by Hjelland in the method of Payumo/Zheng/Schulman. The motivation to do would have been to add immunostimulating activity for a tissue scaffold application. See paragraph [0009].

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-10, 12 and 21-27 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Lambelet whose telephone number is 571-272-1713. The examiner can normally be reached on 8 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEL  
2/27/2007

  
CHRISTINA JOHNSON  
SUPERVISORY PATENT EXAMINER  
3/3/07